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Trends in patented drug prices

Patented Medicine
Prices Review Board



Conseil d'examen du prix
des médicaments brevetés

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Trends in Patented Drug Prices

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Highlights

- Manufacturers' prices of patented drugs declined by 0.1% in 1997, representing the fourth consecutive year of decline. Manufacturers' prices of all drugs (both patented and non-patented) declined by 0.7% in 1997.
- In 1997, only 24% of patented drugs increased in price while 76% stayed the same or went down. This compares sharply to 1992 and earlier when over 60% of patented drug prices went up.
- In 1997, worldwide sales of pharmaceuticals reached over \$400 billion, an increase of 8.6% from the previous year. In Canada, total sales of pharmaceuticals reached \$7.0 billion, an increase of 7.0% from the previous year.
- Sales of patented drugs increased 23% in 1997, to \$3.7 billion.
- In 1997, patented drugs accounted for 52% of total pharmaceutical sales. Previously, patented sales had only accounted for approximately 45% of total sales.
- Newer patented drugs (i.e. patented drugs that have been on the market since 1988) represented almost 90% of total sales of patented drugs in 1997.
- Category 3 drugs made up the lion's share of patented drug sales in 1997 at 47% of the total.
- Overall, Canadian patented drug prices have fallen about 30% relative to foreign prices over the period 1987 to 1997. On average, Canadian prices were 11% below the median international price in 1997.
- Furthermore, 78.3% of Canadian patented drugs were priced below the median international price in 1997. In 1987, only 45% of Canadian patented drugs were priced below the median.
- In 1997, in terms of manufacturers' prices of patented drugs, Canada ranked sixth out of the eight countries in the Regulations. In contrast, in 1987 Canada ranked second.

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1.0 INTRODUCTION

This study reports on trends in prices and expenditures for drug products sold in Canada for the period 1987 to 1997, with a focus on patented drugs.

Patented drug prices are the subject of review by the Patented Medicine Prices Review Board (PMPRB). The PMPRB is responsible for insuring that the prices charged by patentees for prescription and non-prescription patented drugs sold in Canada are not excessive. In most cases that price is the "factory gate" price at which the manufacturer sells the product to wholesalers, hospitals and pharmacies.

The PMPRB is also mandated to collect, collate and report information regarding: price trends for both patented and non-patented drugs; and research and development (R&D) spending in Canada by the patented pharmaceutical industry.¹

The PMPRB has no authority over the prices of non-patented drugs, including generic drugs sold under compulsory licenses. In 1997, patented drugs comprised approximately 52% of manufacturers' sales of all drugs sold in Canada. The remaining 48% are comprised of drugs which have never been patented, or for which a patent has expired. Generic drugs make up approximately 25% of non-patented drugs, or 10% of total drugs sold in Canada.²

In 1997, the PMPRB initiated a consultation process with the release of a Discussion Paper, *Examining the Role, Function and Methods of the Patented Medicine Prices Review Board*. **This study is an important step in this consultation process as it provides stakeholders with the current facts regarding the pricing and expenditure trends of patented drugs sold in Canada and will hopefully facilitate future deliberations regarding the Board's methodologies.** It also presents price and expenditure trends of all drugs, including patented and non-patented drugs.

The analysis is divided into the following sections. Section 2 outlines the methodology used. Section 3 provides general information on manufacturers' sales of all pharmaceuticals in Canada and abroad, as well as sales of patented drugs sold in Canada. Section 4 reports on trends in prices and costs of all drugs in Canada with an emphasis on patented drugs. Section 5 presents the results of international price comparisons for patented drugs. Section 6 provides greater detail on international price comparisons for patented drugs introduced after 1987 and section 7 provides more detail on the relationship of the prices of these drugs in Canada to the other countries.

2.0 METHODOLOGY

As stated above, the PMPRB's regulatory authority applies to the "ex-factory" prices charged by manufacturers of patented medicines. This analysis does not take into account other factors that contribute to the final price a consumer pays for a patented drug, such as the pharmacist's dispensing fee and retail and wholesale mark-ups. It estimated that, on average, the manufacturers' selling price makes up about 60% of the total retail cost of a drug. Wholesale and retail mark-ups and dispensing fees charged by pharmacists make up the remaining 40% of the total retail cost of a drug.³

To conduct the analysis, price and quantity information on all patented drug products filed by patentees under the *Patented Medicines Regulations* were used. These are the prices used by the PMPRB for price review purposes and are described in section 4 of the *Regulations* as:

"(1)(e) ... the average price per package ... in which the medicine was sold by the patentee or former patentee to each class of customer in each province during the periods referred in subsection (2)";

"(4) For the purposes of paragraph (1)(e), in calculating the average price per package of medicine, the actual price after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefits of a like nature and after all deduction of the federal sales tax shall be used."

¹ See the PMPRB's (1998) Tenth Annual Report, for the year ended December 31, 1997, Ottawa: PMPRB.

² See IMS, Canadian Pharmaceutical Market: Drug Store and Hospital Purchases, December 1997. Generic companies include those that belong to the Canadian Drug Manufacturers Association (CDMA).

³ These estimates are based on total manufacturers' sales of patented drugs as filed by patentees with the PMPRB and total expenditures at the retail level from Health Canada's National Health Expenditures, 1996. The estimates are similar to estimates by IMS Canada.

Average transaction prices are calculated by taking the sum of total revenues from sales to all classes of customers (wholesale, retail, hospital, and other) and dividing by total quantities for each drug product.⁴

To measure changes in patented drug prices, the PMPRB maintains the Patented Medicine Price Index (PMPI), an index of the manufacturers' prices for patented drugs as reported annually to the PMPRB. The PMPI is a precise measure of annual price changes for all patented drug products sold in Canada. It is based on a standard Laspeyres methodology used by Statistics Canada.⁵

To report on annual price changes of all drugs, the PMPRB relies on the pharmaceutical component of the Industrial Product Price Index [IPPI (pharma)], published by Statistics Canada.⁶ The IPPI is also based on a Laspeyres methodology and provides an index of manufacturers' prices of all pharmaceuticals including both patented and non-patented drugs.⁷

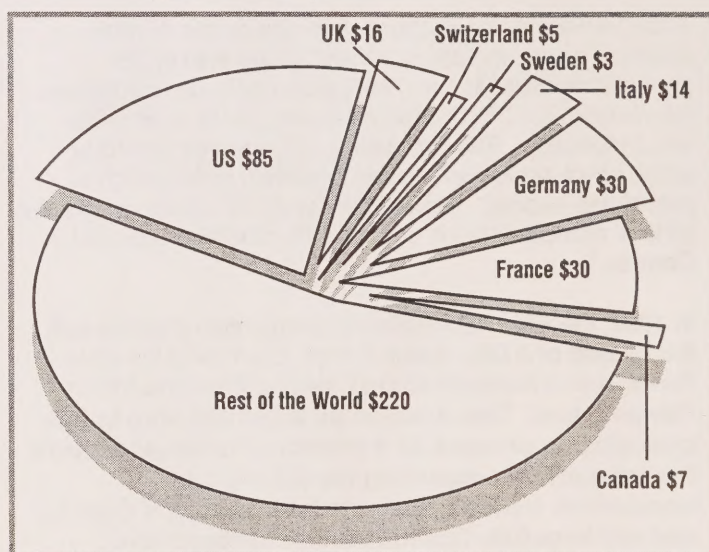
In making an international price comparison, the Board uses average exchange rates for the thirty-six month period prior to the comparison. International price ratios reported in this study are based on an average of the ratio of the Canadian price to median international prices for each patented drug product sold in the respective year.

Because there is considerable variation in sales of different products, the average ratios are weighted by revenues.⁸

3.0 SALES OF PHARMACEUTICALS IN CANADA AND ABROAD

In 1997, it is estimated that worldwide sales of drugs were more than \$400 billion⁹, an increase of 8.6% from 1996.¹⁰ In Canada, total sales of drugs by manufacturers increased by about the same rate, 7.0%, to an estimated \$7.0 billion. As shown in Figure 1, the Canadian market for pharmaceuticals continued to comprise less than 2% of the world market. Figure 1 also shows the proportion of worldwide sales accounted for by the seven countries used by the Board for price review purposes.

Figure 1 Global Sales of Drugs, 1997 (\$411 billion)



Source: SCRIP 1998 Yearbook, Vol. 1

⁴ The price of each drug product includes the price of each strength of each dosage form of a patented medicine. This is normally the level at which Health Canada assigns a Drug Identification Number (DIN) or General Public (GP) number.

⁵ See Statistics Canada Catalogue #62-553 "The Consumer Price Index Reference Paper", 1995, and the PMPRB's "A Description of the PMPI" for a detailed description of the methodology used to construct the chained Laspeyres price index. The Laspeyres methodology is used in the construction of the CPI, IPPI and many other price indices maintained by Statistics Canada.

⁶ The PMPRB and Statistics Canada have formed a Task Force to examine methodological issues surrounding the use of drug price indices.

⁷ Statistics Canada, Cansim # D692600.

⁸ See the PMPRB's *The Impact of Federal Regulation of Patented Drug Prices*, February 1997. This methodology differs slightly from that used in the earlier Top 200 studies conducted by the PMPRB, e.g., PMPRB (1996) S-9607: *The Top 200 Selling Patented Drug Products in Canada, 1994*. In those studies a simple average ratio was calculated rather than a weighted-average ratio.

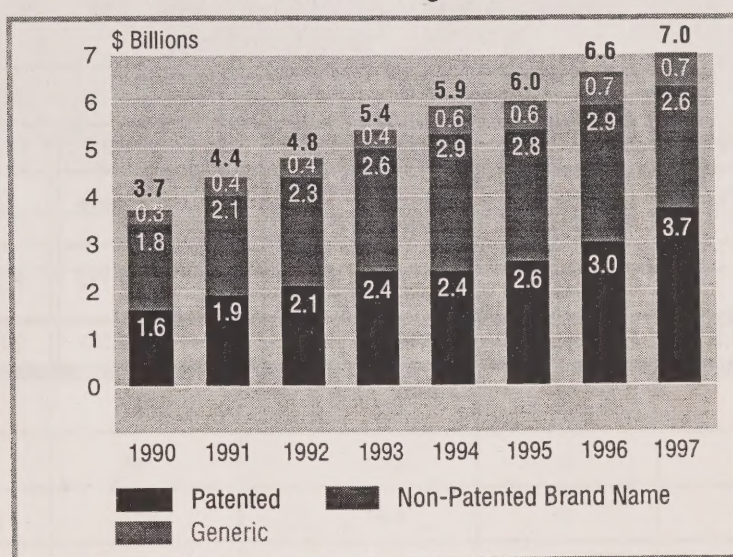
⁹ Unless otherwise specified all currency figures are expressed in Canadian dollars.

¹⁰ SCRIP 1998 Yearbook, Vol. 1, page 124.

As shown in Figure 2, over the period 1990 to 1997, it is estimated that total factory gate sales of pharmaceuticals grew in Canada from \$3.7 billion to \$7.0 billion, an increase of 94.4%. Over the same period, sales of patented drugs grew from \$1.6 billion in 1990 to nearly \$3.7 billion in 1997, an increase of over 130%.¹¹ In 1997 alone, sales of patented drugs increased by almost 23% to \$3.7 billion over 1996. This represented the largest annual growth in sales of patented drugs since the creation of the PMPRB. Total sales of non-patented drugs are estimated to have declined in 1997 by 6% to \$3.3 billion from \$3.6 billion in 1996.

In 1997, the share of patented drugs in total pharmaceutical sales increased to 52%. This is the first time since the creation of the PMPRB that patented drugs accounted for more than 50% of total sales. Previously, patented drug sales comprised between 40% and 45% of total sales. This growth in patented drug sales would appear to be attributed to the increased patent protection resulting from the passage of Bills C-22 and C-91 in 1987 and in 1993.

Figure 2 Manufacturers' Sales of Patented and Non-Patented Drugs 1990-1997



Sources: PMPRB, Statistics Canada and IMS Canada

¹¹ Canada is the only country that regulates drug prices based on patent status. As a result, the information on sales of these drugs is available for Canada and not for other countries.

Table 1 shows the total sales of patented drugs for 1988 to 1997 broken out by sales of "older" drugs and "newer" drugs. For purposes of this analysis, "older" drugs are defined as those being sold as patented drugs in 1987,¹² and "newer" drugs are defined as those that were introduced since then.

It is noteworthy that in 1997, "older" drugs accounted for only \$390 million or 11% of total sales in that year. "Newer" drugs, on the other hand, had sales of \$3.3 billion or 89% of the total sales in that year. This reflects the rapid rate at which newer drugs have replaced older drug therapies. However, it should be noted that as "older" drugs go off-patent, they are no longer included in the PMPRB database even though they still may be sold.

Table 1 Total Patented Drug Sales in Canada, 1988 - 1997 (in millions of dollars)										
	<i>Sales by Year</i>									
	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997
Older Drugs	1,285	1,182	1,166	1,003	896	715	550	481	422	390
Newer Drugs	54	167	435	786	1,176	1,528	1,712	2,095	2,540	3,276
Total	1,339	1,349	1,601	1,789	2,072	2,243	2,262	2,576	2,962	3,666

¹² As these drugs were on the market prior to the creation of the PMPRB in 1987, they were not categorized and their introductory prices were not reviewed by the Board.

For patented drugs that have come on the market since 1987, the Board's guidelines provide for three categories of new patented drug products for purposes of conducting introductory price reviews.¹³ Table 2 breaks out the number of newer drugs by category and the proportion of total sales of patented drugs. Category 1 represents new DINs that are usually a new strength of an existing drug (line extensions); category 2 includes new DINs that are the first drug to treat effectively a particular illness or which provide substantial improvement over existing drug products. These drugs are often referred to as "breakthrough" or "substantial improvement" drugs.

Category 3 include new medicines or new dosage forms of an existing medicine that provide moderate, little or no improvement over existing medicines.

As shown in Table 2, category 3 drugs accounted for the largest sales and number of newer drugs over the period 1988 to 1997. In 1997, 361 category 3 drugs accounted for approximately 47.0% of total sales of patented drugs. Category 2 drugs represented the smallest number of newer drugs during the decade; the 60 category 2 drugs on the market in 1997 represented 12.3% of total sales of patented drugs in that year. Category 1 included 244 drugs and accounted for 27.3% of total patented sales in 1997.

Table 2

**Proportion of Total Sales of Newer Patented Drugs in Canada
By Category, 1988 to 1997**

Year	Category 1		Category 2		Category 3	
	% of Total Sales of Patented Drugs	Number of DINs*	% of Total Sales of Patented Drugs	Number of DINs*	% of Total Sales of Patented Drugs	Number of DINs*
1988	0.4	8	0.5	6	1.4	18
1989	1.6	36	3.6	16	3.8	51
1990	4.5	55	6.3	20	12.2	98
1991	8.3	98	10.2	25	20.9	144
1992	11.2	121	13.3	36	26.6	196
1993	13.7	158	15.9	42	33.8	222
1994	15.8	170	19.5	45	37.9	254
1995	17.4	204	19.6	45	41.5	299
1996	24.8	231	14.3	48	42.2	325
1997	27.1	244	12.3	60	47.0	361

* The number of DINs is the cumulative number of drugs for that category since 1987. DINs that have come off patent or have no sales are not recorded.

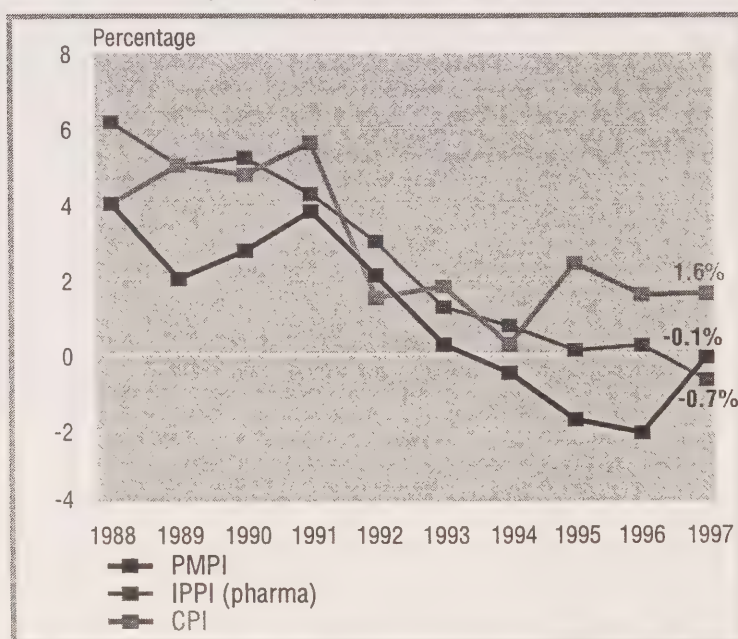
¹³ For complete definitions of the categories, refer to the *Compendium of Guidelines, Policies and Procedures*, Chapter 3, section 3.

4.0 PRICE TRENDS OF PHARMACEUTICALS

Figure 3 shows the year over year changes in the major pharmaceutical price indices over the period 1988 to 1997. The Patented Medicine Price Index (PMPI) is an index which measures the rate of change in manufacturers' prices of patented medicines as reported to the Board. The IPPI (pharma)¹⁴ is the pharmaceutical component of the Industrial Product Price Index, which is compiled by Statistics Canada based on annual surveys of manufacturers of drugs.

As shown in Figure 3, the overall rate of change in the PMPI was lower than the rate of change in the IPPI (pharma) and the Consumer Price Index (CPI) in most years. These trends contrast with the situation prior to 1987 when manufacturers' prices for drugs were increasing considerably faster than the CPI.¹⁵

Figure 3 Year-over-Year Changes in PMPI, IPPI (pharma) and CPI 1988-1997



Sources: PMPRB and Statistics Canada

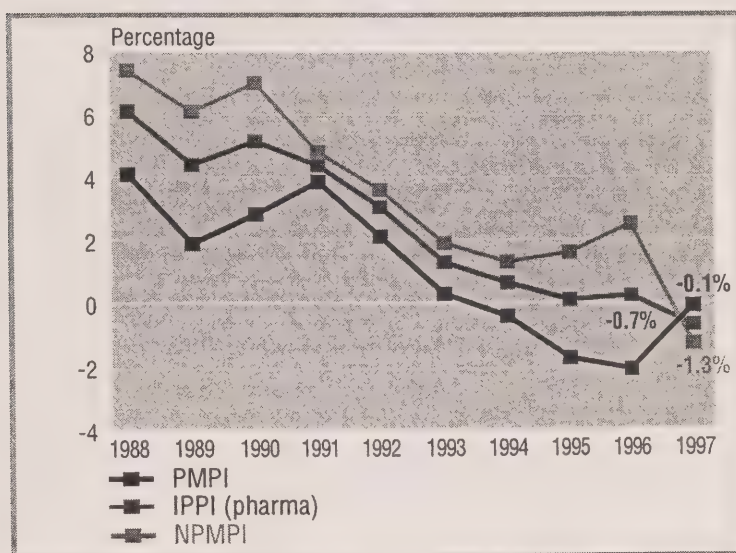
¹⁴ Revised for 1992 to 1996 inclusive. Statistics Canada revised the values of the IPPI (pharma) for those years in October 1997.

¹⁵ PMPRB, Annual Reports.

There is no standard measure or index for prices and price changes for non-patented drugs. It is possible, however, to derive a non-patented medicine price index (NPMPI) from the IPPI (pharma) and the PMPI. To the extent that the IPPI (pharma) is based on a survey, the NPMPI must be treated as being an estimate.

Figure 4 shows the year over year changes in the PMPI, the IPPI (pharma) and the NPMPI over the years 1988 to 1997. This Figure varies slightly for the years 1992 to 1996 from graphs shown in previous reports of the Board because Statistics Canada recently revised the index values for the IPPI (pharma) for those years.

Figure 4 Year-over-Year Changes in the IPPI (pharma), NPMPI and PMPI 1988-1997



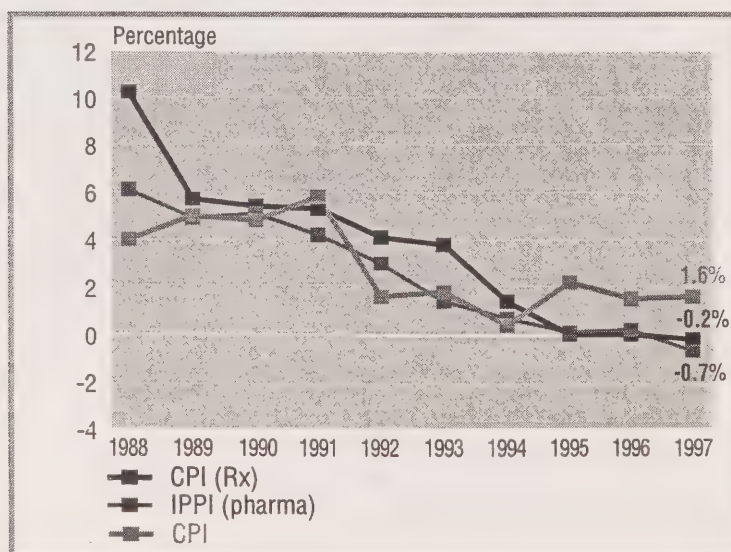
Sources: PMPRB and Statistics Canada

These price indices show changes in the prices charged by manufacturers but, as noted above, those prices represent only a portion of the total price paid by the consumer. Statistics Canada also attempts to track changes in the retail prices of prescription drugs by surveying retail prices at the pharmacy, including markups and dispensing fees for both patented and non-patented drugs. The Consumer Price Index for prescribed medicines, CPI (Rx), is a component of the overall Consumer Price Index.

Figure 5 shows the year over year changes in the CPI, the CPI (Rx), and the IPPI (pharma). These indices, all collected and reported by Statistics Canada, show that the overall rates of change in drug prices at the manufacturers' and retail levels have declined since 1988 although at different rates.

The Board is continuing to work with Statistics Canada in studying and reviewing approaches to measuring rates of change in drug prices.

Figure 5 Year-over-Year Changes in the CPI (Rx), IPPI (pharma) and CPI 1988-1997



Sources: PMPRB and Statistics Canada

4.1 Patented Price Indices: Selected Groups

Table 3 shows the annual changes in prices for the different categories of patented drugs from 1991 to 1997,

as measured by the PMPI. The PMPI was broken out for older drugs, and category 1, category 2 and category 3 drugs. As shown in the Table, all groups demonstrated similar price trends over this time period.

Table 3 Annual Changes in Patented Drug Prices 1991 to 1997							
PMPI	1991	1992	1993	1994	1995	1996	1997
All Drugs	3.8%	2.1%	0.5%	-0.7%	-1.9%	-2.2%	-0.1%
Older Drugs	3.3%	2.8%	0.3%	-1.4%	-2.2%	-1.4%	-0.9%
Category 1	1.0%	-1.5%	-0.4%	-1.2%	-4.2%	-5.1%	-0.1%
Category 2	5.0%	2.2%	0.6%	0.6%	0.5%	0.4%	-0.4%
Category 3	3.2%	3.0%	-0.4%	-0.5%	-1.8%	-2.6%	0.1%

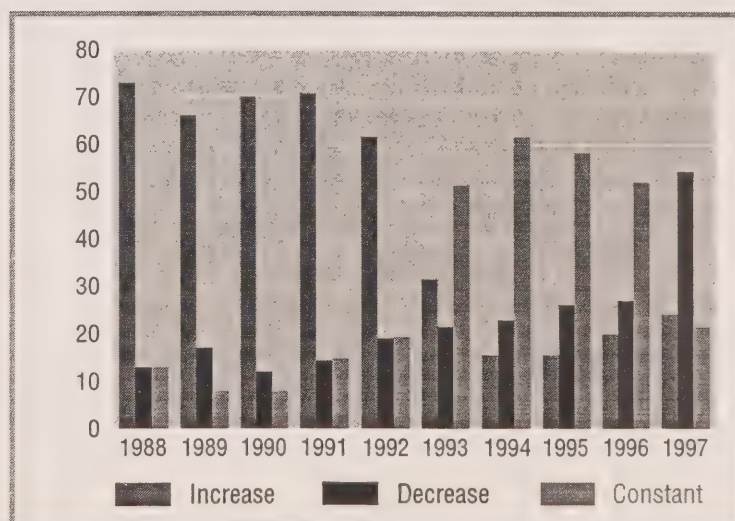
4.2 Patented Drug Prices: By Type of Price Change

Figure 6 shows the proportion of all drugs that went up in price, went down or stayed the same in a given year. In 1988 over 70% of all products went up in price. This pattern changed sharply in 1993, when only 31% of the products increased in price. By 1997, only 24% increased in price while 76% either stayed the same or went down.

The large increase in the number of drug products showing a price decline or no price change in the last four years may be attributed to a number of factors. The PMPRB's Guidelines limit price changes to changes in the CPI. The combination of the guidelines and low inflation resulted in a significant drop in the allowable increases after 1992. In addition, the PMPRB changed its Guidelines, effective in 1994, to limit the cumulative feature of its CPI-adjustment methodology and to ensure that no patented drug product can be priced higher than in other countries. The implementation of these changes caused the prices of more than 100 patented drug products to be frozen or to decline during the years 1994 to 1996. In addition, some provincial drug plans applied measures to

limit price increases in order to contain drug costs. For example, Québec adopted the PMPRB's guidelines for all existing drugs in the early 1990's and Ontario also applied the CPI limit to non-patented drugs in 1993. Ontario froze the prices of all drugs (patented and non-patented) in its formulary as of 1994, and Québec adopted a policy whereby it would not pay prices higher than the lowest price to other provincial drug plans.

Figure 6 Per Cent of Patented Drug Products By Type of Price Change 1988-1997

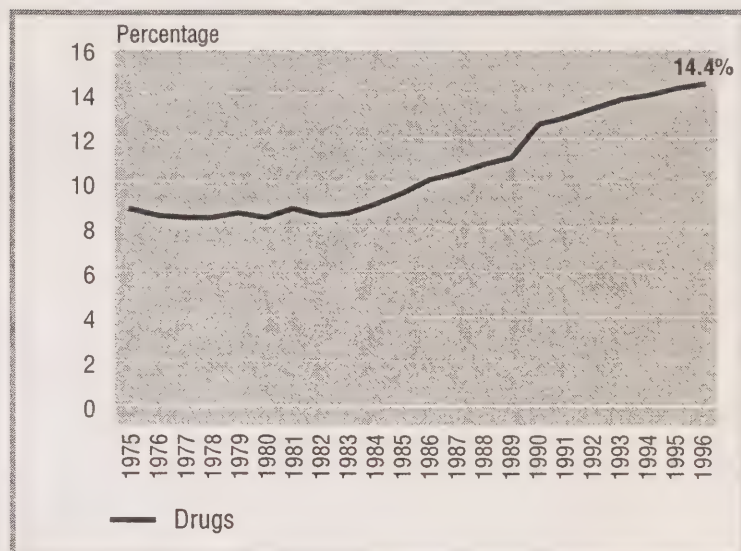


4.3 Comments On Price, Costs and Expenditure Trends

The above price analysis demonstrates that since 1987, manufacturers' prices of all drugs (as represented by the IPPI), and patented drugs (as represented by the PMPI) have increased at an average annual rate of 2.2% and 1.0%, respectively. Despite these modest annual increases in drug prices, expenditures on pharmaceuticals have been increasing more rapidly.

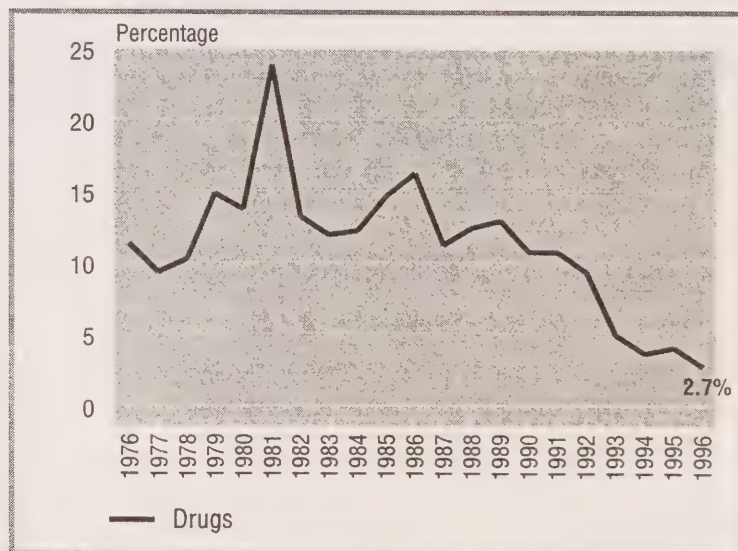
Figure 2 showed that total factory gate sales of pharmaceuticals increased at an average annual rate of 11% from 1990 to 1997. Health Canada has also reported that total expenditures on drugs have been increasing faster than prices. While the rate of increase in drug expenditures has declined from more than 10% in the early 1990's to 2.7% in 1996, drugs still represent the fastest growing component of health care (see Figures 7 and 8). These data underscore a common point of confusion relating to the substantial increase in pharmaceutical expenditures on the one hand and the more moderate increases in prices on the other hand.

Figure 7 Drug Expenditures as a Percentage of Total Health Expenditures 1975-1996



Source: Health Canada

Figure 8 Year-over-Year Changes in Drug Expenditures 1976-1996



Source: Health Canada

Because there is no single drug plan in Canada, there is no single source of information on trends in the cost of prescriptions to consumers. However, the experience of public and private plans appears to be consistent with the information reported in the National Health Expenditures and by Statistics Canada. For example, analysis by Green Shield¹⁶ has shown that between 1987 and 1993 its average annual cost per claim rose 93% for an annual average rate over the six years of 11.6%. More recently, the Canadian Wholesale Drug Association¹⁷ has reported that the average cost per claim in Ontario over the period 1992/3 to 1996/7 rose 17.6%, for an average annual increase of 4.4% per year. While no similar comprehensive price index exists at the retail level, the CPI (Rx) shown in Figure 5 shows that retail prices for prescriptions have moderated substantially since 1994.

These analyses demonstrate that price increases of drugs are only **one factor** behind the rising costs (expenditures) of pharmaceuticals overall. **Other factors** include:¹⁸

- changes in utilization of drugs;
- changes in prescribing habits of physicians;
- a tendency to prescribe and use newer and more expensive drugs;
- a trend towards using drug therapy instead of other treatments;
- changes in total population;
- changes in demographics and health status of the population; and,
- the emergence of new diseases to be treated and old diseases which can now be treated more effectively.

All these factors have an independent impact on rising drug costs over time. This means that control of one factor (e.g. drug prices at the factory gate) does not necessarily mean control of total expenditures.

5.0 INTERNATIONAL PRICE COMPARISONS

In determining if the price of a patented drug product is excessive, the *Patent Act* requires the PMPRB to consider the prices of the drug in other countries, along with other factors. Consistent with that requirement, the Guidelines rely on international price comparisons for the review of the introductory prices of some new medicines.

The PMPRB has published analyses of international price comparisons for the top selling patented drugs since 1992. In the first international price comparison of patented drug prices, it was found that Canadians were often paying more for patented drug products than citizens in any other reference country. Effective in 1994, the PMPRB amended its Guidelines to put greater emphasis on international price comparisons for new and existing drugs, with the objective that prices, on average, should not exceed median international prices.

The foreign prices used for the PMPRB's regulatory purposes, and in this analysis, are ordinarily the prices filed by patentees as required by the *Patented Medicines Regulations*. Section 4 of the *Regulations* requires patentees to submit information showing, in part:

"4.(1)(g) Where the medicine is being sold in one or more of the countries set out in Schedule 1, the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold to each class of customer in each of those countries..."

(10) For the purpose of this section, 'publicly available ex-factory price' includes any price of a patented medicine that is agreed upon by the patentee or former patentee and the appropriate regulatory authority of the country in which the medicine is sold by the patentee."

For purposes of comparisons, the foreign price is calculated as the simple average of the prices to different classes of customers in the country converted to Canadian currency by using the average exchange rate over the previous 36 months. See also PMPRB *Verification of Foreign Patented Drug Prices*, S-9812, 1998.

¹⁶ Green Shield Canada (1994) "A Report On Drug Costs".

¹⁷ Canadian Wholesale Drug Association's *Industry Trends Report 1998 - Ontario and Quebec*.

¹⁸ See the Federal Provincial Territorial (F/P/T) Task Force's forthcoming report on *Cost Drivers in Pharmaceuticals in Canadian Provincial Drug Plans*, and the PMPRB Discussion Paper "Examining the Role, Function and Methods of the Patented Medicine Prices Review Board", Section 2, November 1997.

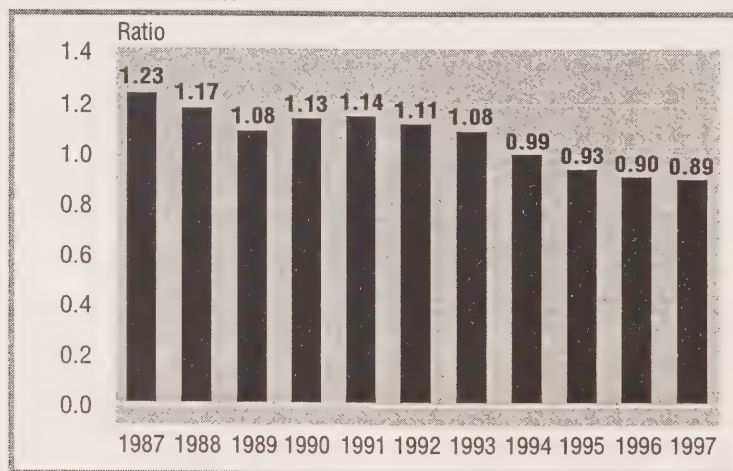
5.1 Relationship of Canadian Prices to Foreign Prices: Past and Present

Overall, Canadian patented drug prices have fallen compared to foreign prices over the period 1987 to 1997. Figure 9 shows that the average ratio of Canadian prices to median foreign prices has declined from 1.23 in 1987 to 0.89 in 1997. This represents a fall of about 30% in Canadian prices relative to other countries over this time period.

As noted above, the Board amended its guidelines several years ago because Canadian prices for patented drugs, on average, were above the median of foreign prices. These changes were announced in 1993, following a year of public consultations, and phased in during 1994 to 1996.

Table 4 provides a summary of the instances when Canadian prices for patented drugs were being the highest and lowest of the seven countries and the number below the median of the foreign prices over this time period. In 1997, 708 out of 904, or 78.3% of patented drug products in Canada were priced below the median international price. In 1987, only 45% were priced below the median international price. The number of cases where Canada was the highest among the seven countries has also declined sharply over this period. In 1987, Canadian prices were highest in 21.5% of the cases, but this dropped to only 2.0% in 1996 and only 1.7% in 1997.¹⁹ In addition, Canadian prices were lowest in 51.5% of the cases in 1997, a substantial increase from 24.8% in 1987.

Figure 9 Ratio of Prices for Patented Drugs in Canada to Median International Prices 1987-1997



Source: PMPRB

¹⁹ The Board's Guidelines now provide that the price of a patented drug in Canada may not be higher than the highest price in other countries. The cases identified in 1996 and 1997 where the Canadian price was the highest were either under investigation, or there was insufficient grounds for the Board to commence proceedings.

Table 4 also shows that Canadian prices, on average, were below median international prices for all patented drug products since 1994. In 1996 and 1997 Canadian patented prices were, on average, 9 and 11 percentage

points, respectively, below the median international price. As shown above, this represents a contrast from 1987 when Canadian patented prices were, on average, 23% above the median international price.

Table 4

**International Price Comparisons of Patented Drug Products
1987 to 1997**

Year	Number of Drug Products	Can. Price Highest		Can. Price Lowest		Below Median		Ratio of Avg. Can Price to Median
		#	%	#	%	#	%	
1987	427	92	22	106	25	192	45	1.23
1988	477	91	19	143	30	226	47	1.17
1989	539	100	19	151	28	270	50	1.08
1990	603	130	22	181	30	303	50	1.13
1991	642	158	25	180	28	302	47	1.14
1992	699	153	22	20	29	366	52	1.10
1993	816	114	14	288	35	480	59	1.08
1994	798	61	8	319	40	539	68	0.98
1995	814	27	3	369	45	599	74	0.94
1996	943	17	2	439	52	664	79	0.91
1997	904	15	2	433	52	708	78	0.89

Table 5 compares Canadian prices to prices in each of the foreign countries listed in the *Regulations*. It demonstrates the percentage of cases where the Canadian price was below the price in the foreign country and the average ratio of Canadian to foreign price for the years 1987, 1992 and 1997.

As seen in Table 5, in 1987 Canadian patented drug prices were higher than in all other countries except the U.S. After 1987 Canada improved its position dramatically against every country. In 1997 Canada improved its position to rank behind the U.S., Switzerland, Germany, Sweden and the United Kingdom.

Table 5

Patented Drug Products - 1987, 1992 and 1997
By Country
Canadian Prices to Foreign Prices

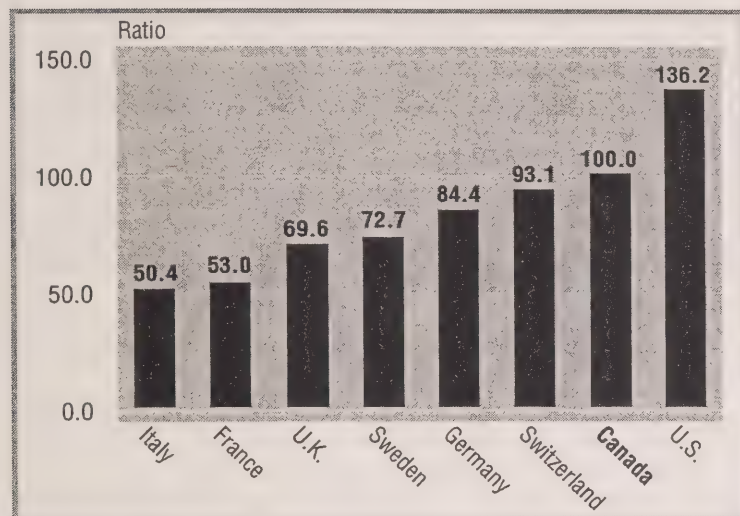
Comparison Country	1987		1992		1997	
	% Canada Below	Average Ratio	% Canada Below	Average Ratio	% Canada Below	Average Ratio
France	19.7	1.98	44.7	1.53	59.8	1.12
Germany	54.7	1.17	65.5	1.02	78.8	0.90
Italy	32.2	1.97	38.9	1.29	38.8	1.26
Sweden	35.9	1.37	50.1	1.19	62.8	0.94
Switzerland	51.1	1.08	67.5	1.03	80.9	0.81
U.K.	32.2	1.44	46.5	1.22	58.7	0.99
U.S.	74.0	0.74	87.7	0.81	96.8	0.64
Median	47.8	1.23	67.5	1.10	78.6	0.89

Figures 10 and 11 use the same information to demonstrate more clearly the changes in Canada's ranking with respect to prices of patented drugs in other countries over this period.

Figure 12 demonstrates how prices changed in each country by type of price movement for 1997. The analysis

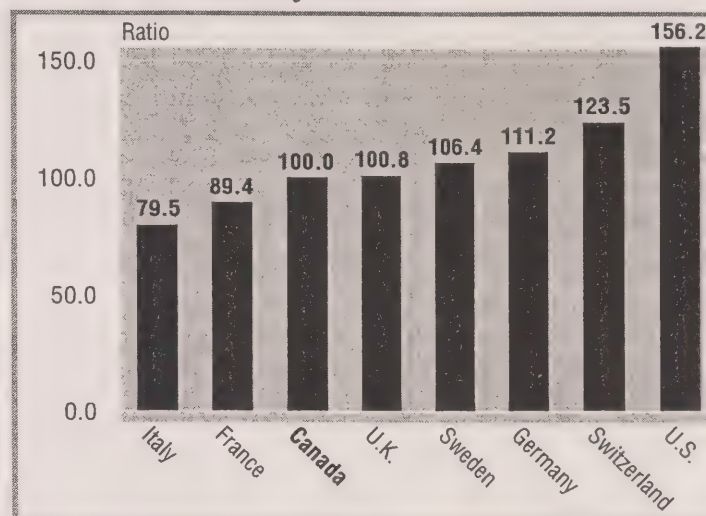
was done by tracking annual domestic price changes in local currency of each country. As shown in Figure 12, in Canada, the prices of 76% of patented drug products remained the same or fell in 1997 and 24% increased. This compares to increases for 20.4% in the U.K., 23.4% in France, 24.2% in Switzerland, 24.4% in Germany, 28.7% in Sweden, 40.6% in Italy, and 62.6% in the U.S.

Figure 10 Average Foreign to Canadian Price Ratios
All Patented Drug Products in 1987



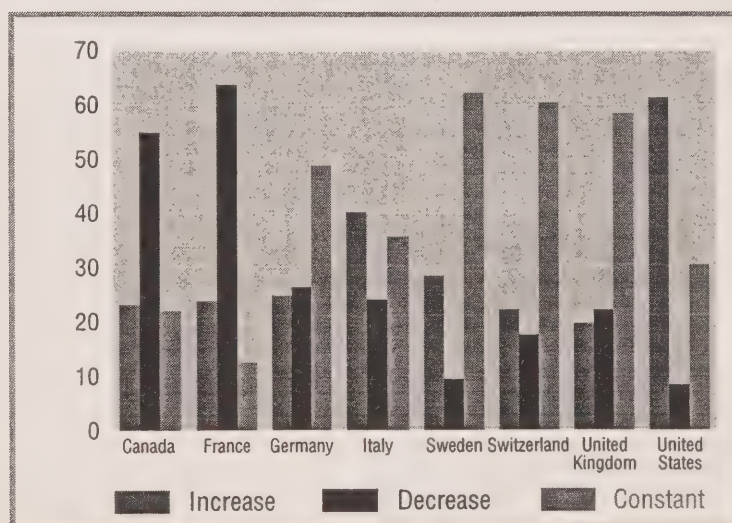
Source: PMPRB data, weighted by net sales

Figure 11 Average Foreign to Canadian Price Ratios
All Patented Drug Products in 1997



Source: PMPRB data, weighted by net sales

Figure 12 Price Changes of Patented Drug Products in Canada and Other Countries By Type of Price Movement in 1997



6.0 INTERNATIONAL PRICE COMPARISONS: BY CATEGORY

This section reports on the relationship between Canadian prices and median international prices for those patented drugs that have been categorized (Category 1, Category 2 and Category 3) over the period 1990 to 1997.

Table 6 demonstrates that for all categories of patented drug products, Canadian prices declined relative to the foreign median over the period 1990 to 1997. The prices of category 2 drug products (substantial improvement and breakthrough medicines) had the lowest price relative to the median, both with respect to the number of products and the ratio of Canadian prices to median international prices. This has special significance given that this group often comprises the more costly new medicines. In 1997, the ratio of Canadian to median international prices of category 2 products was 0.8, i.e., Canadian prices of these products were, on average, 20% below median international prices. This is down sharply from the early 1990's when these products were equal to or slightly above the median international prices. With respect to the number of cases, in 1997, 51 out of 52 or 96.8% of these drug products were priced below the median international price. This represents a significant improvement from 1990 when 75.0% of category 2 drugs were priced below the median.²⁰

The fact that category 2 products, the more innovative, have continued to be priced below the median international prices has important implications because these products may establish new therapeutic classes. Under the PMPRB's Guidelines the introductory prices of most subsequent entries into a therapeutic class would not be able to exceed the price of the first drug. This is partly reflected in the downward trend in Canadian prices relative to foreign prices shown for category 1 and category 3 drug products. In 1997, 81.0% of the drug products for category 1 and 75.7% of the drug products for category 3 were below the median international prices. In contrast, in 1990, only 52.7% and 48.5% of category 1 and category 3, respectively, were below the median international prices.

In addition, in 1996 and 1997, all categories of drug products were, on average, priced below the median international price. As shown in Table 6, the ratio of Canadian prices to median international prices was 0.89 for category 1 and 0.93 for category 3 in 1997.

²⁰ The Guidelines limit the price of a new drug in category 2 to the higher of the median international price or the other drugs in the therapeutic class. A category 2 drug may be priced higher than the foreign median if its price has gone up in Canada, within the increase in the CPI, and prices declined elsewhere, or if the existing drugs in Canada that treat the same disease were more expensive than in other countries.

Table 6

**Patented Drug Products - 1990, 1994, and 1997
International Price Comparison
of Drugs Introduced since 1987, by Category**

Category	1990		1994		1997	
	% Below Median	Ratio of Canadian to Median	% Below Median	Ratio of Canadian to Median	% Below Median	Ratio of Canadian to Median
1	52.7	1.19	73.1	0.92	81.0	0.89
2	75.0	0.98	83.7	0.89	96.8	0.78
3	48.5	1.20	64.1	1.09	75.7	0.93
Total	52.8	1.14	69.6	0.99	79.6	0.89

7.0 FURTHER PRICE ANALYSIS OF NEW DRUGS

In its Discussion Paper on the role, function and methods of the PMPRB, the Board asked questions regarding its pricing methods and guidelines. In particular, three issues were raised regarding the means by which introductory prices for new medicines are reviewed: The Highest Price Rule; Median International Price Test; and, the Therapeutic Class Comparison test.²¹

The following analysis provides background information for further deliberations regarding the Board's methodologies.

7.1 The "Highest Price Rule"

The use of the "highest price rule" was implemented in 1994, after consultation with stakeholders. It provides an additional test for international price review of all new and existing drug products (i.e. Canadian prices of new or existing patented medicines are not allowed to exceed the highest price of the same medicine sold in all countries listed in the *Regulations*). The objective of introducing this amendment to the Guidelines, in addition to the existing

provisions, was to ensure that prices of patented drugs in Canada, on average, would be no greater than the median of foreign prices.²² Questions were raised however that this rule might allow non-breakthrough drugs (i.e., category 1 and 3) to be priced above the median even though breakthrough drugs (category 2) are generally required to be priced no higher than the median.

As shown in Table 6, 19.0% of Category 1 and 24.3% of Category 3 drugs were priced above the median in 1997. This represents a shift from 1990, when 47.5% of Category 1 and 51.5% of Category 3 drugs were priced above the median. With respect to Category 2 drugs, only one drug in 1997 was priced above the median.²³

Tables 7 to 9 demonstrate the relationship of Canadian prices relative to the highest price country for Categories 1, 2 and 3 drugs. For example, in Table 9, only 5 out of 354 Category 3 drugs were priced highest among the comparator countries. Furthermore, when Canadian prices were the second highest, they were between 54% and 68% of the highest price, depending on the number of countries. Similar results are seen for Category 1 drugs.

²¹ The use of the Therapeutic Class Comparison (TCC) to review the prices of category 3 new drugs is dealt with in a separate report. See *Category 3 Drug Prices: A Preliminary Outline of Issues*.

²² See PMPRB Bulletin No. 12, page 4, September 1993.

²³ See footnote 20.

Table 7

**Ratio of Canadian Prices Relative to the Highest International Prices
By Number of Comparator Countries and By Canada's Price Rank
For Category 1 Drug Products In 1997**

Canada Price Rank	1 Country		2 Countries		3 Countries		4 Countries		5 Countries		6 Countries		7 Countries	
	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs
Highest	1.29	1	1.2	2	1	1	0	0	1.1	1	0	0	0	0
2 nd Highest	0.62	69	0.7	8	0.7	12	0.8	4	0.7	6	0	0	0.6	1
3 rd Highest			0.6	22	0.6	3	0.4	2	0.7	1	0.7	6	0.8	4
4 th Highest					0.5	11	0.5	10	0.6	2	0.5	1	0.7	2
5 th Highest							0.5	13	0.5	10	0.5	3	0.6	3
6 th Highest									0.4	12	0.6	12	0.7	4
7 th Highest											0.4	13	0.5	5
Lowest													0.3	10
ALL	0.63	70	0.7	32	0.6	27	0.5	29	0.5	32	0.5	35	0.5	29

Table 8

**Ratio of Canadian Prices Relative to the Highest International Prices
By Number of Comparator Countries and By Canada's Price Rank
For Category 2 Drug Products In 1997**

Canada Price Rank	1 Country		2 Countries		3 Countries		4 Countries		5 Countries		6 Countries		7 Countries	
	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs
Highest	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2 nd Highest	0.8	7	0.7	1	0	0	0	0	0	0	0	0	0	0
3 rd Highest							0.6	2	0	0	0	0	0	0
4 th Highest									0.8	1	0.6	1	0	0
5 th Highest							0.3	2	0.6	3	0.6	1	0.5	1
6 th Highest									0.5	6	0.8	2	0.7	7
7 th Highest											0.5	5	0.6	11
Lowest													0.6	9
ALL	0.8	7	0.7	1	0	0	0.7	4	0.6	10	0.6	9	0.6	28

Table 9

**Ratio of Canadian Prices Relative to the Highest International Prices
By Number of Comparator Countries and By Canada's Price Rank
For Category 3 Drug Products In 1997**

Canada Price Rank	1 Country		2 Countries		3 Countries		4 Countries		5 Countries		6 Countries		7 Countries	
	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs	Avg Cdn/ High	No of DINs
Highest	1.1	2	1.2	1	0	0	0	0	0	0	1.1	2	0	0
2 nd Highest	0.6	64	0.5	10	0.6	6	0.7	11	0.6	15	0.7	9	0.6	6
3 rd Highest			0.6	11	0.6	5	0.7	10	0.6	7	0.5	2	0.7	7
4 th Highest					0.6	20	0.6	7	0.7	6	0.6	11	0.5	7
5 th Highest							0.6	22	0.6	13	0.6	11	0.6	6
6 th Highest									0.6	14	0.6	8	0.6	13
7 th Highest											0.5	22	0.5	8
Lowest													0.5	18
ALL	0.6	66	0.6	22	0.6	31	0.6	50	0.6	55	0.6	65	0.6	65

7.2 The Median International Price Test

In its Discussion Paper, the Board asked if the median international price test was still appropriate for Category 2 drugs. During the consultations, questions were raised about whether, even if Canada's prices for these drugs are in line with the seven countries listed in the *Regulations*, Canadians are receiving good "value". The subject of determining value will be the subject of further consultations. In addition, concern was raised regarding the number of cases where prices in Canada were compared to fewer than five countries, i.e. how many times are only one or two countries being used to establish the maximum non-excessive prices of Category 2 drugs.

Table 10 demonstrates the relationship of Canadian prices relative to the median price by number of countries for Category 2 drugs. As shown in the Table, Canadian prices consistently ranked among the lower priced countries. Furthermore, the number of occasions when the drug products was being sold in fewer than five of the other countries was only 12 out of 59 in 1997.

Table 10

**Ratio of Canadian Prices Relative to the Median International Prices
By Number of Comparator Countries and By Canada's Price Rank
For Category 2 Drug Products In 1997**

Canada Price Rank	1 Country		2 Countries		3 Countries		4 Countries		5 Countries		6 Countries		7 Countries	
	Avg Cdn/ Med.	No of DINs	Avg Cdn/ Med	No of DINs	Avg Cdn/ Med.	No of DINs	Avg Cdn/ Med.	No of DINs	Avg Cdn/ Med.	No of DINs	Avg Cdn/ Med	No of DINs	Avg Cdn/ Med.	No of DINs
Highest	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2 nd Highest	0.8	7	0.9	1	0	0	0	0	0	0	0	0	0	0
3 rd Highest							1.11	2	0	0	0	0	0	0
4 th Highest									1	1	1	1	0	0
5 th Highest							0.64	2	0.8	3	0.8	1	0.88	1
6 th Highest									0.6	6	0.9	2	0.88	7
7 th Highest											0.7	5	0.77	11
Lowest													0.66	9
ALL	0.8	7	0.9	1	0	0	0.87	4	0.7	10	0.8	9	0.77	28

Glossary

Note To Reader: This glossary is included for the convenience of the reader. For more detailed information and definitions please refer to the *Patent Act*, the *Patented Medicines Regulations (1994)*, the *Compendium of Guidelines, Policies and Procedures*, or contact the PMPRB.

Average Transaction Price (ATP): The weighted average of all of the ex-factory prices paid by the various buyers in all markets in Canada, net of discounts, rebates and free goods. This is the unit of measurement used by the PMPRB to determine the maximum non-excessive price (MNE; see definition below). Note that the ATP may not necessarily resemble the actual price charged in a given marketplace (i.e. the actual price at the retail pharmacy level, for instance, may be slightly higher or lower than the MNE). As long as the ATP is within the Guidelines, the price is said to be "non-excessive."

Category 1 Medicine: A new DIN of an existing dosage form of an existing medicine, or a new DIN of another dosage form of the medicine that is comparable to the existing dosage form.

Category 2 Medicine: A new DIN of a non-comparable dosage form of an existing medicine or the first DIN of a new chemical entity, that provides a **breakthrough** (i.e. the first product to be sold in Canada that treats effectively a particular illness or addresses effectively a particular indication) or **substantial improvement** (i.e. relative to other products sold in Canada, the product provides increased efficacy or major reductions in dangerous adverse reactions; or provides significant savings to the Canadian health care system) over comparable existing DINs.

Category 3 Medicine: A new DIN of a non-comparable dosage form of an existing medicine or the first DIN of a new chemical entity, that provides moderate, little or no therapeutic advantage over comparable existing DINs; includes those new drug products that are not included in Category 2 above.

Drug Identification Number (DIN): A registration number that the Health Protection Branch of Health Canada assigns to each prescription and non-prescription drug product marketed under the *Food and Drug Regulations*. The DIN is assigned using information in the following areas: manufacturer of the product; active ingredient(s); strength of active ingredient(s); pharmaceutical dosage form; brand/trade name; and route of administration.

Drug Product: A particular presentation of a medicine characterized by its pharmaceutical dosage form and the strength of the active ingredient(s).

Drug Product, Existing: An existing patented drug product (DIN) is one for which a benchmark price has been established in accordance with the Board's Guidelines. (See Chapter 1, subsection 3.3 of the *Compendium of Guidelines, Policies and Procedures*.)

Drug Product, New: A new patented drug product (DIN) is one for which the introductory price is under review. Drug products are considered new in the year during which they are introduced in Canada. For price review purposes, new drug products for 1996 are those introduced between December 1, 1995 and November 30, 1996. Because of the filing requirements under the *Patented Medicines Regulations* and the manner of calculating benchmark prices, drug products introduced in December are considered to have been introduced in the following year. (See Chapter 1, subsection 3.2 of the *Compendium of Guidelines, Policies and Procedures*.)

Existing Product: DINs for which a benchmark price has been established in accordance with the PMPRB's Guidelines.

Factory Gate Price (i.e. ex-factory or manufacturer price): The price that the manufacturer charges for the drug as the drug leaves the factory, per tablet, capsule, etc. This price may not be reflective of what the end consumer pays, as mark-ups/distribution costs/fees may be added along the way.

Generic Product: A drug product with the same active ingredient, strength and dosage form of a brand name drug product.

International Price is calculated for each drug product in each foreign country in which it is sold. It is defined as a simple average of the unit ex-factory prices reported by patentees, these prices can vary by package size and by class of customer.

Maximum Non-excessive Price (MNE): The maximum average transaction price that a patentee is allowed to charge and still be within the conditions set out under the Guidelines. (Also see definition for average transaction price [ATP] above.)

Median International Price is calculated for each drug product, and is defined as the international price with an equal number of international prices that are higher as

there are international prices lower. For instance, if a drug is sold in all seven comparator countries, the fourth highest price is the median price as there are three countries with higher prices and three countries with lower prices. If the drug product is sold in an even number of countries the median price is defined as the simple average of the two mid-points. For instance if the drug product is only sold in six comparator countries, the median price an average of the 3rd highest price and the 3rd lowest price.

Medicine: Any substance or mixture of substances made by any means, whether produced biologically, chemically, or otherwise, that is applied or administered *in vivo* in humans or in animals to aid in the diagnosis, treatment, mitigation or prevention of disease, symptoms, disorders, abnormal physical states, or modifying organic functions in humans and or animals, however administered.

For greater certainty, this definition includes vaccines, topical preparations, anaesthetics and diagnostic products used *in vivo*, regardless of delivery mechanism (e.g., transdermal, capsule form, injectable, inhaler, etc.). This definition excludes medical devices, *in vitro* diagnostic products and disinfectants that are not used *in vivo* (Compendium of Guidelines, Policies and Procedures, Introduction, subsection 1.5).

Net Revenues consist of actual sales revenue (excluding sales tax) for medicine sold (i.e. shipped) during the reporting period less amounts disbursed for benefits or promotions such as rebates, refunds, or gifts.

New Drug Product: A category 1, 2 or 3 medicine (see above; also see **Drug Product, New** definition above).

Patent: An instrument issued by the Commissioner of Patents in the form of letters patent for an invention that provides its holder with a monopoly limited in time, for the claims made within the patent. A patent gives the patentee the exclusive right to make, sell or otherwise exploit the invention for the term of the patent.

Patented Medicines Price Index (PMPI) is a modified-chained Laspeyres price index developed by the PMPRB to measure price inflation of patented drug prices. The PMPI compares the prices of individual drug products from one year to the next. PMPI does not reflect changes in prescribing patterns or the replacement of older therapies by newer medicines.

Patentee: As defined by subsection 79(1) of the *Patent Act*, "the person for the time being entitled to the benefit of the patent for that invention (pertaining to a medicine) and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a licence continued by subsection 11(1) of the *Patent Act Amendment Act*, 1992, that other person in respect of those rights;"

Prescription Fee: A flat fee charged by the pharmacy for dispensing each prescription medication.

Prescriptions Medicines: Medicines that are usually prescribed by a physician, dispensed by a pharmacist and received either in hospital or in the community.

Price: The unit cost of the drug alone, on a per tablet, capsule, etc. basis.

Research and Development (R&D): Basic, applied, clinical and pre-clinical research for the purpose of creating new, or improving existing, materials, devices, products or processes (e.g., manufacturing processes).

Retail Drug Cost/Price: This is the total charge that consumers and other payers pay for a prescription and is comprised of the factory gate price, distribution costs and retails costs (including any retail mark-ups and dispensing fees).

Thirty-six month average exchange rates are used by the PMPRB to smooth over daily fluctuations in the rates of currency exchange. The 36-month exchange rates are calculated as the average of previous 36 monthly averages of the noon spot exchange rates. The 36-month exchange rates are updated each month. The exchange rates used in this document are in turn the average of the 12 36-month average exchange rates in each year.

Total drug expenditures (also known as total drug costs, or the total drug bill): From the perspective of a provincial pharmacare system, these costs/expenditures refer to the total of the following: the price of all drugs, the added mark-ups and dispensing fees that are charged for those drugs; and the total utilization (i.e. the total prescribing) of all drugs covered by the pharmacare system.

Wholesaler or Retailer Markup (or distribution costs): A percentage of the factory gate price that the wholesaler and/or retailer adds to that price in order to cover the costs of warehousing, transporting, and other costs related to distributing the medication.



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